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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/661,696	09/14/2000	Tina Meinertz Andersen	6028.200-US	8978

7590

11/05/2002

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EXAMINER

MOHAMED, ABDEL A

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 11/05/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/661,696

Applicant(s)

ANDERSEN, TINA MEINERTZ

Examiner

Abdel A. Mohamed

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 October 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 14-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 and 14-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

ACKNOWLEDGMENT OF PRELIMINARY AMENDMENT, IDS AND STATUS OF THE CLAIMS

1. The preliminary amendment and the Information Disclosure Statements (IDS) and Form PTO-1449 filed 9/14/00 and 10/19/01, respectively are acknowledged, entered and considered. In view of Applicant's request claim 13 has been canceled, claims 1-12 have been amended and claims 14-20 have been added. Thus, claims 1-12 and 14-20 are now pending in the application.

CLAIM REJECTION-35 U.S.C. § 112^{2nd} PARAGRAPH

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5 and 14-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 is indefinite in the recitation "various MAS which is selected from the group comprising....." because "comprising" is an open ended and it is not clear if Applicant intends a Markush format. If Applicant intends to use a Markush format, then, the Office recommends the use of the phrase ".....selected from the group consisting of....." in listing species to ensure that the Markush group is "closed".

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Claims 14-20 are indefinite in the recitation the content of water, organic solution and MAS, respectively in percentages only because there is inconsistency with claims 2-4 which recite the content of water, organic solution and MAS, respectively in percentages with (weight/weight). Also, for further support in regard to consistency, See pages 2, lines 7-12 and lines 15-18 19 in the instant specification. Thus, appropriate correction is required.

CLAIMS REJECTION-35 U.S.C. § 102(b)

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-12 and 14-20 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 98/24883).

WO 98/24883 discloses similarly a solid composition comprising meiosis activating substance (MAS) and an additive, wherein the additive and organic solvent are components when added to MAS provide a composition which can be used to prepare an aqueous containing MAS. The preferred MAS is FF-MAS molecule which is 4,4-dimethyl-5 α -cholesta-8,14,24-triene-3 β -ol. With respect to the percentages content of water, organic solvent; the prior art does not disclose the above percentages content as claimed. However, the ranges disclosed in the prior art overlaps the claimed ranges. Further, it is the Examiner's position that since the above

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characteristics (i.e., percentages content) are in the properties and not in the structure of the claimed formulation/composition claimed, and as such it is inherent characteristics/properties of the prior art composition/formulation (See e.g., page 1, lines 5-31 ; pages 7-12, and the claims).

In regard to claim 12 which is directed to a device comprising a hollow containing the claimed composition, the prior art discloses the teaching of growing culture medium in a hollow container, and as such, the delivery system has a container or a hollow device containing the composition of MAS and additive for the purpose of growing cells thereof. Thus, the reference clearly discloses a composition comprising MAS and additive of which can be dissolved in the aqueous medium in with a culturing system of a device containing a hollow composition thereof, and as such anticipates claims 1-12 and 14-20 as drafted.

5. Claims 1-12 and 14-20 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 00/52142).

WO 900/52142 discloses similarly a solid composition comprising meiosis activating substance (MAS) and an additive, wherein the additive and organic solvent are components when added to MAS provide a composition which can be used to prepare an aqueous containing MAS. The preferred MAS is FF-MAS molecule which is 4,4-dimethyl-5 α -cholesta-8,14,24-triene-3 β -ol. With respect to the percentages content of water, organic solvent; the prior art does not disclose the above percentages content as claimed. However, the ranges disclosed in the prior art overlaps the claimed ranges. Further, it is the Examiner's position that since the above

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characteristics (i.e., percentages content) are in the properties and not in the structure of the claimed formulation/composition claimed, and as such it is inherent characteristics/properties of the prior art composition/formulation (See e.g., pages 2-11 and the claims).

In regard to claim 12 which is directed to a device comprising a hollow containing the claimed composition, the prior art discloses the teaching of growing culture medium in a hollow container, and as such, the delivery system has a container or a hollow device containing the composition of MAS and additive for the purpose of growing cells thereof. Thus, the reference clearly discloses a composition comprising MAS and additive of which can be dissolved in the aqueous medium in with a culturing system of a device containing a hollow composition thereof, and as such anticipates claims 1-12 and 14-20 as drafted.

6. Claims 1-12 and 14-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Byskov et al. (U.S. Patent No. 5,716,777).

Byskov et al. disclose similarly a solid composition comprising meiosis activating substance (MAS) and an additive, wherein the additive and organic solvent are components when added to MAS provide a composition which can be used to prepare an aqueous containing MAS. The preferred MAS is FF-MAS molecule which is 4,4-dimethyl-5 α -cholesta-8,14,24-triene-3 β -ol. With respect to the percentages content of water, organic solvent; the prior art does not disclose the above percentages content as claimed. However, the ranges disclosed in the prior art overlaps the claimed ranges. Further, it is the Examiner's position that since the above

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characteristics (i.e., percentages content) are in the properties and not in the structure of the claimed formulation/composition claimed, and as such it is inherent characteristics/properties of the prior art composition/formulation (See e.g., cols 2-4, Examples 1-5 and claims 1-4).

In regard to claim 12 which is directed to a device comprising a hollow containing the claimed composition, the prior art discloses the teaching of any mode of administration which encompass injection, spray in liquid or powder form, ect., and as such, the delivery system has a container or a hollow device containing the composition of MAS and additive for the purpose of administration thereof. Thus, the reference clearly discloses a composition comprising MAS and additive of which can be dissolved in the aqueous medium in with a delivery system of a device containing a hollow composition thereof, and as such anticipates claims 1-12 and 14-20 as drafted.

CONCLUSION AND FUTURE CORRESPONDENCE

7. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abdel A. Mohamed whose telephone number is (703) 308-3966. The examiner can normally be reached on Monday through Friday from 5:30 a.m. to 5:00 p.m. The examiner can also be reached on alternate Fridays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on (703) 308-2923. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Abdel A. Mohamed
ABDEL MOHAMED
PATENT EXAMINER
GROUP 1800
TC 1600

AM Mohamed/AAM

November 4, 2002